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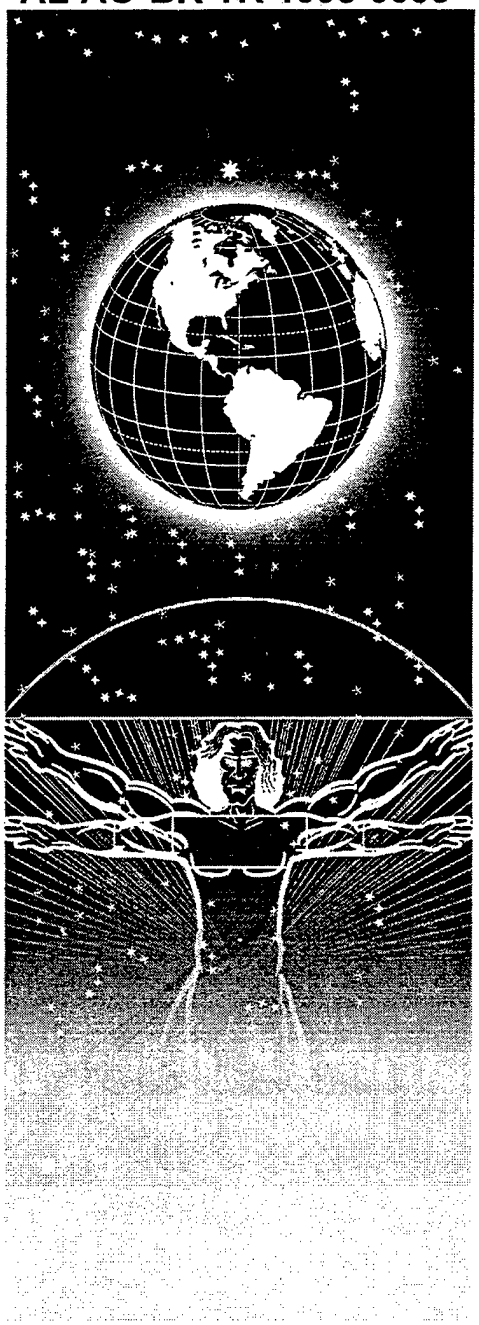

UNITED STATES AIR FORCE
ARMSTRONG LABORATORY

Testing and Evaluation of the Modified Gentex Mask Assembly in the Hyperbaric Environment

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April 1998

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NOTICES

This final technical report was submitted by personnel of the Davis Hyperbaric Laboratory, USAF School of Aerospace Medicine, 311th Human Systems Wing, Air Force Materiel Command, Brooks Air Force Base, Texas.

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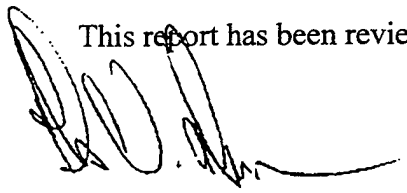
The Office of Public Affairs has reviewed this report, and it is releasable to the National Technical Information Service, where it will be available to the general public, including foreign nationals.

This report has been reviewed and is approved for publication



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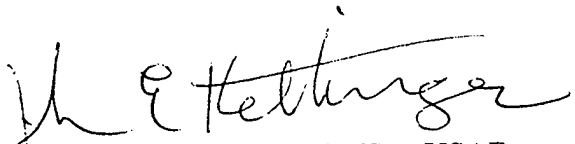

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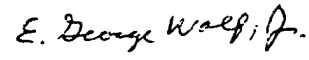

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REPORT DOCUMENTATION PAGE	Form Approved OMB No. 0704-0188

1. AGENCY USE ONLY *(Leave blank)*	2. REPORT DATE	3. REPORT TYPE AND DATES COVERED
	April 1998	Final, February 1996 - April 1997

4. TITLE AND SUBTITLE
Testing and Evaluation of the Modified Gentex Mask Assembly in the Hyperbaric Environment

5. FUNDING NUMBERS

6. AUTHOR(S)
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7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
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8. PERFORMING ORGANIZATION REPORT NUMBER
AL-AO-BR-TR-1998-0038

9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)

10. SPONSORING/MONITORING AGENCY REPORT NUMBER

11. SUPPLEMENTARY NOTES

12a. DISTRIBUTION AVAILABILITY STATEMENT
Approved for public release; distribution is unlimited.

12b. DISTRIBUTION CODE

13. ABSTRACT *(Maximum 200 words)*

BACKGROUND: Since the late 1970's Air Force hyperbaric facilities have been utilizing the MBU 5/P aviator's mask with a unique hyperbaric adapter assembly as a way to safely exhaust exhaled breathing gas from inside a high pressure chamber to ground level ambient pressure. Although the MBU 5/P mask, developed in the 1950's, is still available through depot, the modified adapter assembly is not. In order to purchase additional units, the adapter assembly must be re-milled at considerable expense to the government. Recently developed mask technology has evolved new systems which may provide increased comfort and reduced maintenance at less cost to the government.

METHODS: The Modified Gentex Mask Assembly (MGMA) was evaluated by hyperbaric technologists at 3.0, 2.4 and 2.0 ATA using a pressure demand regulator, pressure transducers and a mass spectrometer to determine if the MGMA could physiologically maintain levels of inspired oxygen while also exhausting expired carbon dioxide and other exhaled gases to ambient pressure.

RESULTS: Equipment testing has identified the MGMA as a suitable substitute for implementation at Air Force and possibly civilian hyperbaric facilities.

CONCLUSION: Inspiratory and expiratory gas analysis indicate the MGMA and current A-14 regulator constitute a highly efficient oxygen delivery system for hyperbaric use. MGMA met or exceeded industry standards established by Sheffield, Stork and Morgan. Currently, the MGMA is being modified for improvements by the Gentex Corporation.

14. SUBJECT TERMS	15. NUMBER OF PAGES
Hyperbaric Chamber Mask, Oxygen System, Oxygen Overboard Dump System, Oxygen Mask	22
	16. PRICE CODE

17. SECURITY CLASSIFICATION OF REPORT	18. SECURITY CLASSIFICATION OF THIS PAGE	19. SECURITY CLASSIFICATION OF ABSTRACT	20. LIMITATION OF ABSTRACT
Unclassified	Unclassified	Unclassified	UL

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ACKNOWLEDGMENTS

The author is indebted to the enlisted and officer members who provided their time, equipment and technical assistance during the testing and evaluation of the Modified Gentex Mask Assembly:

Major Don Diesel
MSgt Butch Blake
TSgt Roy Cano
SSgt David Case
Mr. Ron Holden
Mr. Billy Jackson
Krug Laboratory
Davis Hyperbaric Laboratory Staff

TESTING AND EVALUATION OF THE MODIFIED GENTEX MASK ASSEMBLY IN THE HYPERBARIC ENVIRONMENT

PURPOSE AND OBJECTIVES

The purpose of this evaluation was to assess the suitability of the Modified Gentex Mask Assembly's (MGMA) safe use in the hyperbaric environment. The objectives were to determine if the MGMA could: 1) maintain a seal (no leakage) at various pressure settings, 2) maintain proper levels of oxygen, and carbon dioxide and 3) ensure mask cavity pressure was maintained at a suitable level at various treatment depths.

BACKGROUND

The modified 1950's era MBU 5/P aviator's mask with its unique hyperbaric adapter assembly is the only patient/inside attendant oxygen breathing mask approved for use in Air Force hyperbaric chambers (Fig 1). Rothe Industries specifically developed the adapter assembly in the late 1970's for Air Force use. At the time, the modified mask assembly provided the only known method to safely exhaust exhaled breathing gas from inside a high pressure chamber to lesser, outside ground level pressure. Although the MBU 5/P mask is still available through depot, the modified adapter assembly is not. In order to purchase additional units, the adapter assembly must be re-milled at considerable expense to the government. Recently developed mask technology has evolved new systems which are less costly, provide increased comfort, enhance field of view, and require less maintenance than the current system.

As the Department of Defense Lead Agent for clinical hyperbaric medicine, the Davis Hyperbaric Laboratory in collaboration with the Gentex Corporation modified a Combat Edge HA/LP derivative MBU-20-P mask for use in the hyperbaric environment. The Modified Gentex Mask Assembly was tested and evaluated at clinical operational pressures. Throughout this report the acronym MGMA refers to the Modified Gentex Mask Assembly.

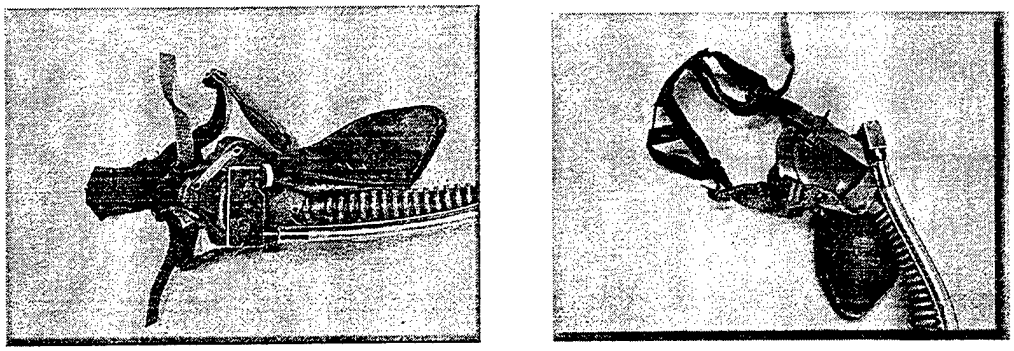

Figure 1

DESCRIPTION

The MGMA (Combat Edge HA/LP derivative) is a portable, lightweight, low profile design featuring side entry and exit hoses (Fig 2).

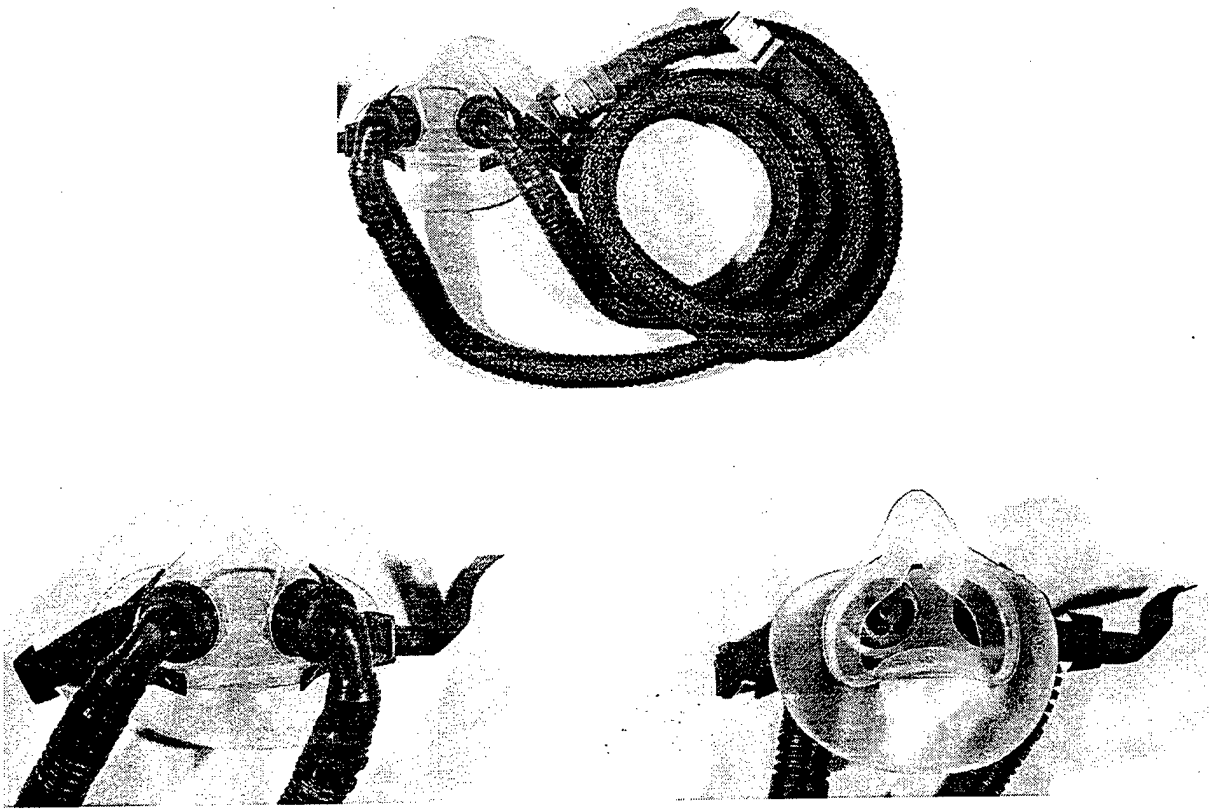

Figure 2

The face seal is molded from soft, pliable silicone rubber available in either clear or colored texture. The face seal comes in four sizes; small narrow, medium narrow, medium wide and large wide. The face seal flange seals between the lower lip and chin. The hard-shell assembly is equipped with valsalva port openings, and is fabricated from approximately .060 inch thick clear polycarbonate. The mask is now manufactured with a clear blue tint. The mask incorporates separate inhalation and exhalation valves for easier breathing. The inhalation valve was designed to meet or exceed military specifications for leakage and flow rate requirements for aviation.

The exhalation valve is modified with a lock ring extension sleeve to facilitate expiration (Fig 3).

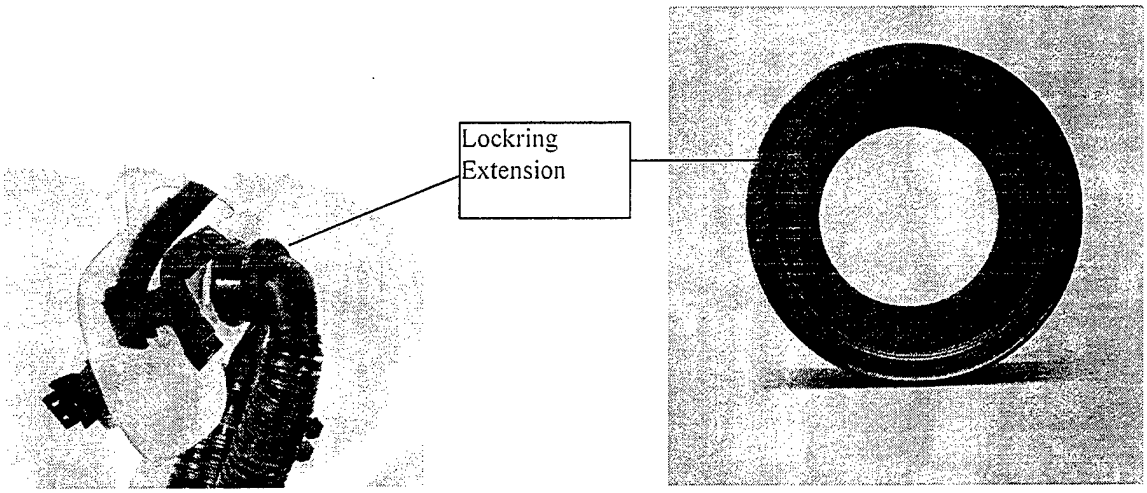

Figure 3

The inhalation and exhalation hoses consist of corrugated flexible oxygen grade tubing. Both the inhalation/exhalation tubing have a 3/4 inch thermoplastic shutoff high flow quick coupling on the end (Fig 4).

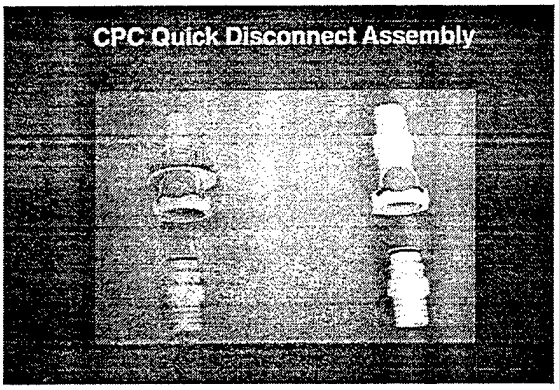

Figure 4

The exhalation tubing can be equipped with an adapter tee and swage lock quick disconnect fitting to the overboard dump system (Fig 5). **NOTE: Not evaluated during testing.**

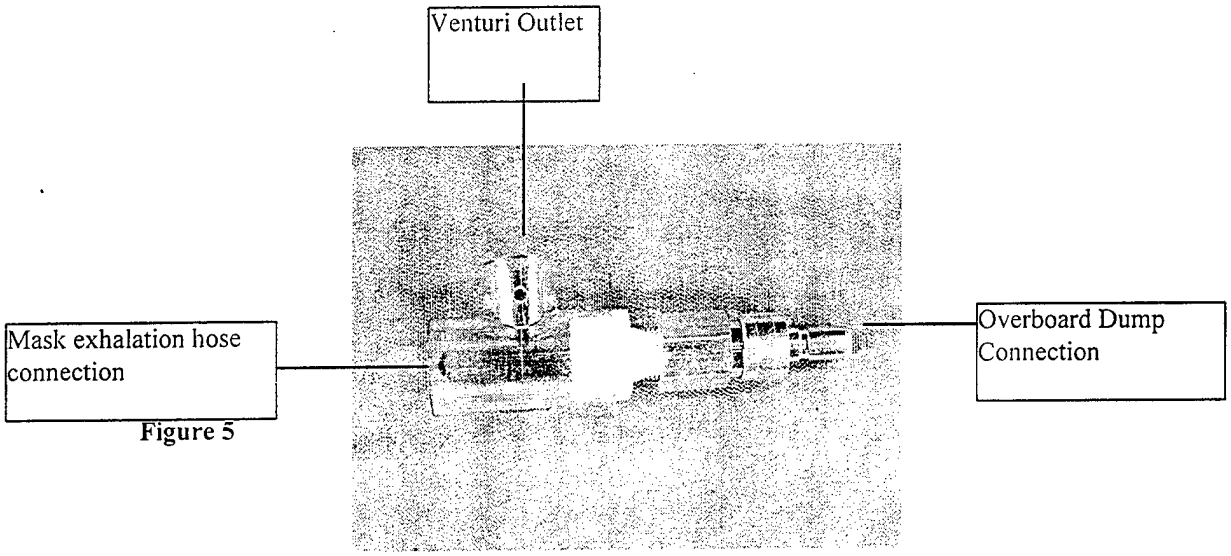

Figure 5

The mask is equipped with a mesh skullcap, having a Velcro® strap and hook/loop arrangement for easy donning and removal (Fig 6).

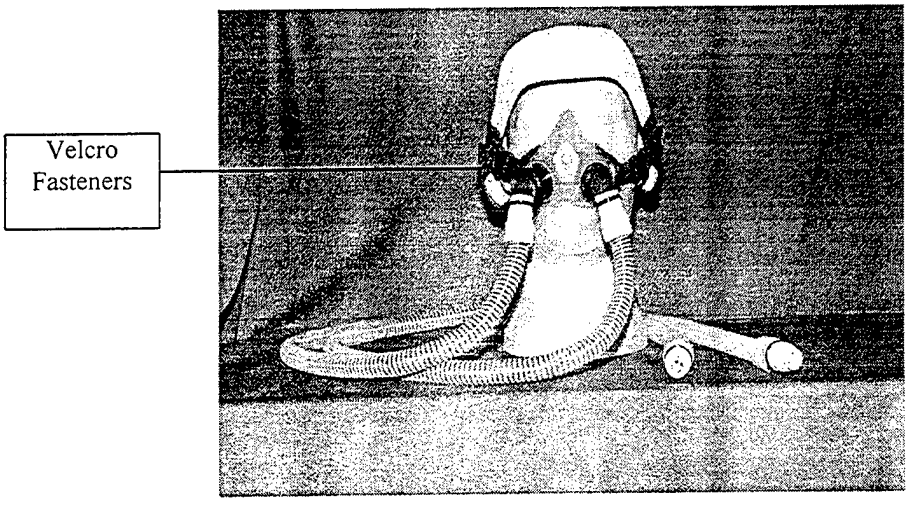

Figure 6

TEST EQUIPMENT

Operational testing of the MGMA with human subjects was conducted in the Panama chamber at the Davis Hyperbaric Laboratory, Armstrong Laboratory, Brooks AFB, Texas, from January 1997 through April 1997. The following equipment used during testing and evaluation of the two MGMA's.

1. Modified Gentex Mask Assembly (MGMA) Size Small and Medium (See Fig. 2)

2. Cole Palmer Pressure Calibrator (Model PCL-200)

3. Face Caliper

4. Gould Strip Chart Recorder (Model 2400)

5. Perkin Elmer Mass Gas Spectrometer (Model 1100)

   Specifications: Accuracy O_2 = +/- 1%
   CO_2 = +/- 1%

Oxygen calibrations checked using ambient air equal to 21% oxygen. Specific calibration gases used as a reference for calibration of CO_2.

6. A-14 Oxygen Regulator

7. Plastic Douglas-Type Gas Collection Bags Size: 200-Liter Capacity

8. Gentex LSIT-1/A Mask Tester

9. Fleisch Pneumotachograph Size: 2 (up to 99 liters per minute)

10. Validyne Carrier Demodulator (Model CD-12) (3 ea.)

11. Validyne Differential Pressure Transducer (Model DP-45)

12. Validyne Differential Pressure Transducer (Model DP-15) (2 ea.)

13. Labview Data Acquisition System (LDAS)

Specifications: The LDAS is a microcomputer with multitasking capability, real-time data acquisition, and a high-resolution graphic display. An A/D board provides sixteen channels of analog to digital conversion at a rate of 500 samples per channel, two digital to analog channels, and eight digital input and output lines.

PROCEDURES

Test methods and performance criteria were derived from various military standards (Reference List 4-6), nationally recognized performance guidelines (7) and manufacturer's literature (5). Air Force Instruction 40-403 Using Human Subjects in Research, Development, Test, and Evaluation describes the human interface issues to be considered during equipment testing (2) .

The basic specifications of the MGMA outlined by manufacturer and researcher were tested and evaluated at standard ambient conditions (Phase 1), and in the hyperbaric environment (Phase 2). During testing, the mask assembly was subjectively evaluated for comfort, durability, leaks, user operating procedures, breathing resistance and objectively measured for flow rates, oxygen and carbon dioxide percentages.

The MGMA was tested at ground level and various hyperbaric pressures to observe and evaluate performance under anticipated operational conditions.

1. Initial Inspection/Test Preparation
2. Test Configuration
3. Experimental Protocol
    a. Phase I (Ground Level Base Line Testing)
    b. Phase II (Subject Exposure Profile)
        1. 3.0 ATA
        2. 2.4 ATA
        3. 2.0 ATA

INITIAL INSPECTION AND TEST PREPARATION

a. The MGMA was inspected for quality of workmanship, production techniques and possible damage incurred during shipment.

b. The MGMA was placed on the face of a human subject and connected to the Gentex LSIT-1/A Mask Tester. Both test masks were tested for leaks prior to test configuration and

checked for safety requirements and operating characteristics established by the manufacturer.

TEST CONFIGURATION

The diagram below describes the configuration of test equipment used during evaluation and testing of the MGMA during Phase I and II.

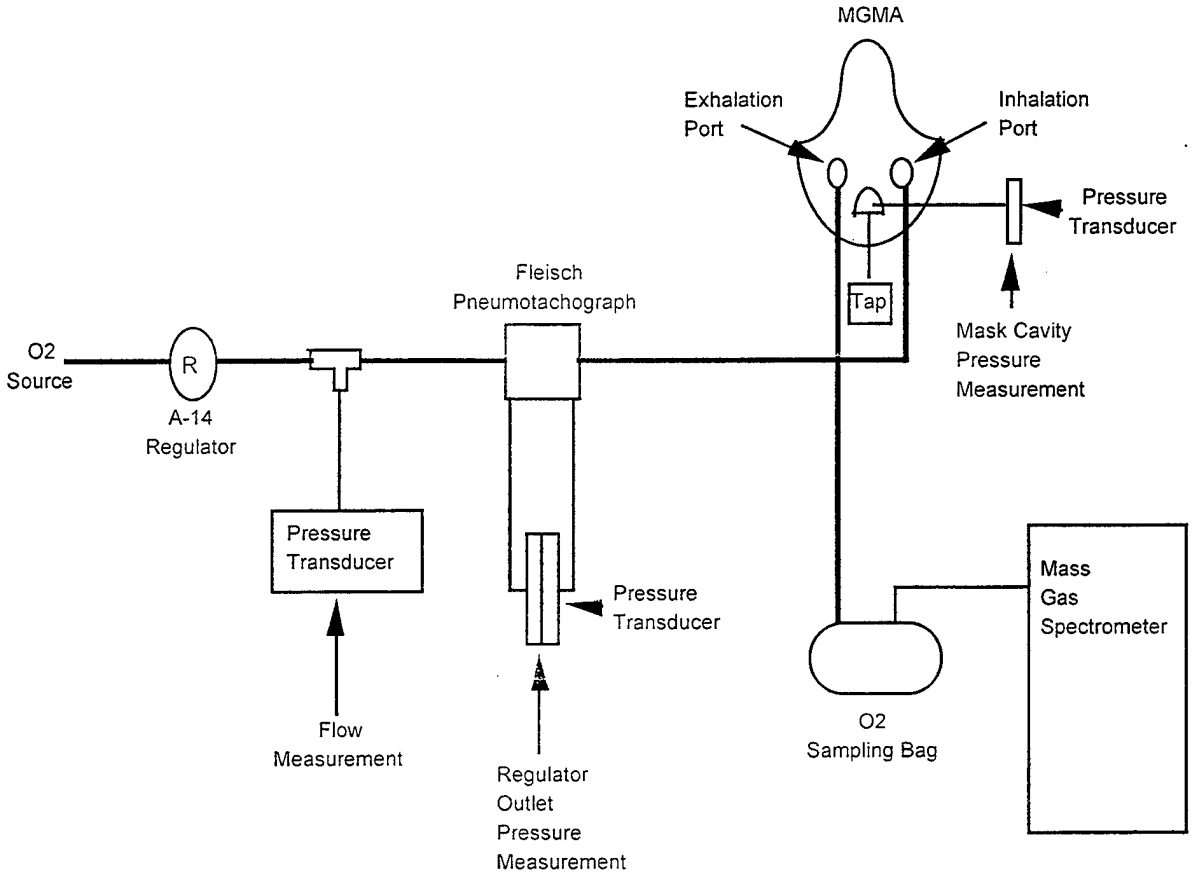

Figure 7

EXPERIMENTAL PROTOCOL

Phase I & II Objectives

Testing was conducted in two Phases. Phase I consisted of ground level tests, and Phase II consisted of tests at 2.0, 2.4, and, 3.0 ATA. At each depth, subjects were required to breath for two minutes on each of the following regulator settings: on-demand, 1" H_2O, 1.5" H_2O, and 4.0" H_2O. During each breathing cycle, the mask was assessed for its ability to maintain a seal (no leakage), ability to provide adequate flow and pressure at the various depths, and ability to maintain specified levels of oxygen and carbon dioxide within the mask cavity at each of the regulator settings. Finally, each subject provided a subjective evaluation of inhalation/exhalation resistance of the mask at the various depths and pressure settings.

Six healthy volunteer subjects, five male and one female from Armstrong Laboratory qualified for exposure in a high-pressure vessel environment, were selected to participate in this preliminary assessment. Some relevant physical and equipment sizing characteristics of the subjects are described in Table 1. Subjects were selected based on their ability to obtain a "mask seal" using a small or medium-sized MGMA. The participants were volunteers and were briefed on the objective and nature of the experiment. Each participant signed a written consent prior to initiation of the study.

TABLE 1. PHYSICAL & EQUIPMENT CHARACTERISTICS OF SUBJECTS

SUBJECT	SEX	AGE(Y)	MASK SIZE
1	F	44	Small
2	M	29	Medium
3	M	37	Small
4	M	36	Small
5	M	40	Small
6	M	26	Medium
	Mean:	35 ± 9	Small

Prior to compression, each subject was trained on proper operating procedures for the MGMA mask assembly and A-14 regulator. Subjects were fitted with fire protective coveralls, and briefed on chamber safety per test requirements in accordance with AOH Operating Instructions 167-1 (O_2 Delivery System). Inside observers ensured subjects maintained a proper mask seal throughout testing.

PHASE I

Ground Level Testing: Subjects were seated inside the Panama hyperbaric chamber and connected to equipment described in the test configuration. Mask cavity oxygen concentration, flow rate, regulator outlet pressure and inhalation/exhalation resistance were measured for all six subjects . A total of twelve tests were conducted, using 100% aviator's breathing oxygen from the normal, "s", "ty", and 41m settings of the A-14 regulator. Subjects breathed a minimum of two minutes at each setting to ensure equilibration of gas mixtures inside the mask cavity. These measurements were later used as a baseline measurement for analysis of test results. Upon completion of sea level measurements testing proceeded to Phase II.

PHASE II

At Depth Testing: The same six Phase 1 subjects were exposed to 3.0, 2.4 and 2.0 ATA during a single pressurization. (See below)

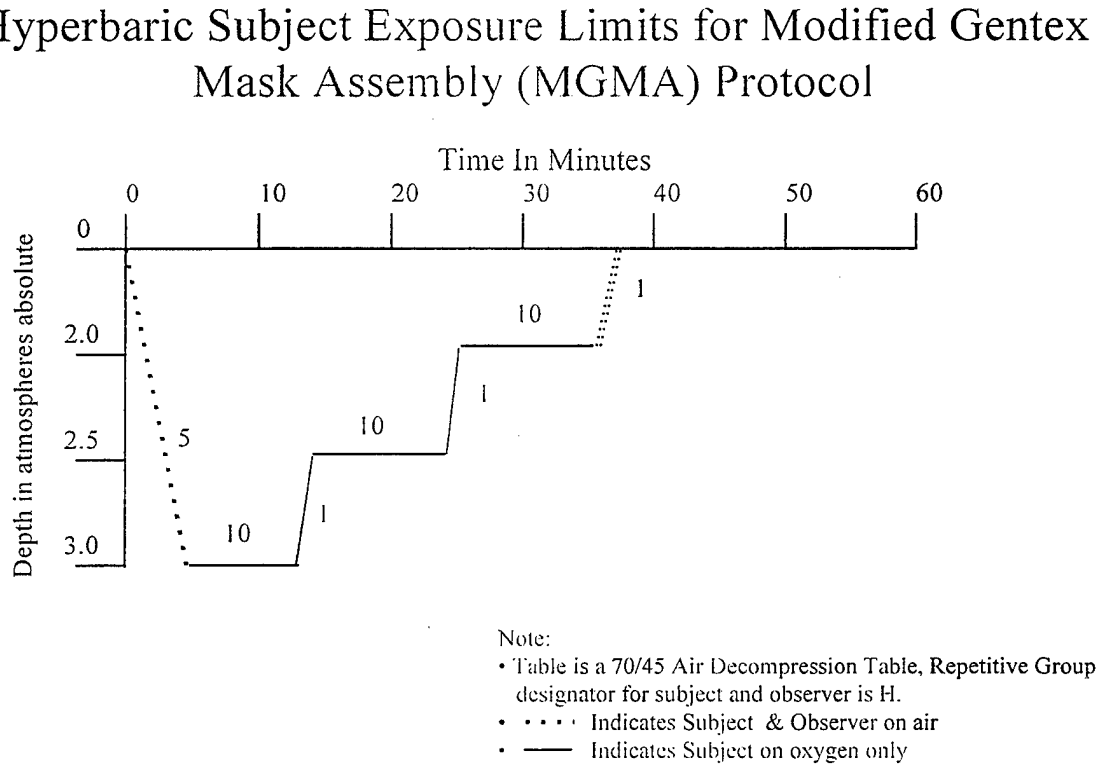

Figure 8

The procedures described in Phase I testing were re-accomplished at 3.0, 2.4 and 2.0 ATA. A total of twelve tests were conducted at these increased barometric pressure levels. The only significant difference between phase I and Phase II testing was the introduction of increased pressure variables.

RESULTS

Characteristics of the subjects (N=6) on which complete data were obtained are shown in Table 1 . The mean values for sex, age and mask size were typical of those reported for this age group.

Mean expired oxygen/carbon dioxide and breathing resistance responses to various ambient and increased pressure levels are featured in Figures 8, 9, 10 and 11 which are broken down according to the A-14 regulator pressure setting; normal, "s", "ty", and 41m settings.

Mean Expired Oxygen Levels

Atmospheres	Oxygen Concentration Percentages
1 ATA	84 -90 %
2 ATA	91 - 95 %
2.4 ATA	89 - 95 %
3 ATA	87 - 95 %

Figure 9. The mean oxygen percentage of the six subjects using the normal, "s", "ty", and 41m pressure settings of the A-14 regulator at different pressures.

Mean Expired Carbon Dioxide Levels

Atmospheres	Carbon Dioxide Concentration Percentages
1 ATA	3.0 - 3.3 %
2 ATA	1.3 - 1.5 %
2.4 ATA	1.1 - 1.2 %
3 ATA	0.9 - 1.1 %

Figure 10. The mean carbon dioxide percentage of the six subjects using the normal, "s", "ty", and 41m pressure settings of the A-14 regulator at different pressures.

The primary purpose of this study was to determine if the MGMA could maintain a seal (no leakage), and measure the amount of oxygen, carbon dioxide and breathing resistance of the mask at increased barometric pressures. In particular, we anticipated that the oxygen and carbon dioxide percentages would be different at the various pressure and regulator settings. For the purpose of examining these contrasts, subjects were tested in two phases. Phase I testing was completed at sea-level (1 ata) to establish a base line and Phase II was accomplished under increased barometric pressure. As anticipated, the graph below (Figure 11) indicates that as pressure increased the percentage of expired oxygen increased with carbon dioxide remained relatively the same.

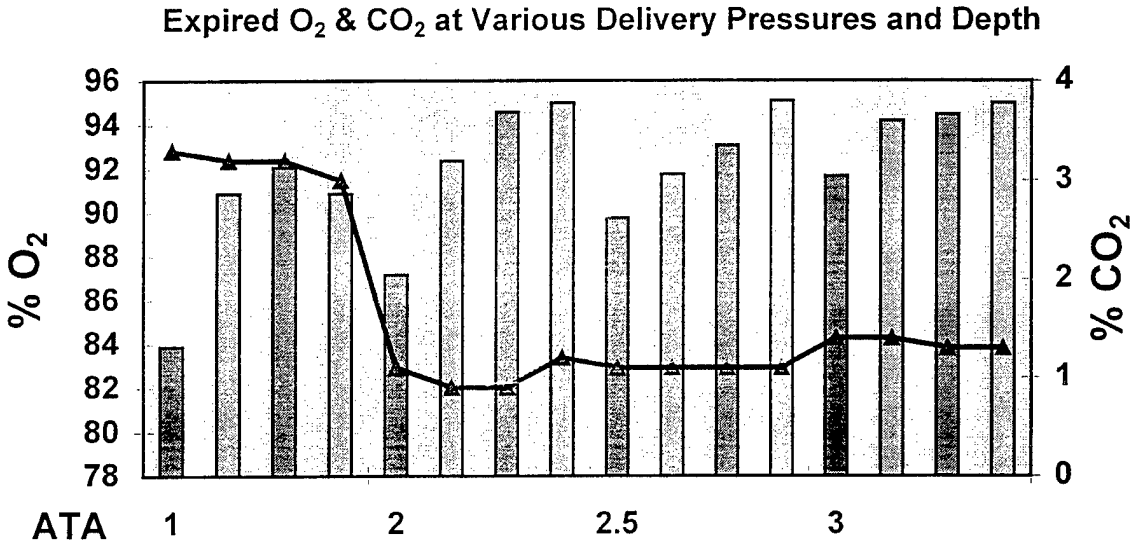

Figure 11. Bar lines reflect the four pressure setting of normal, "s", "ty", and 41m of the A-14 Regulator. Normal = On Demand, "S" = 1.0" H_20, "TY" = 1.75 H_20 and "41M = 4.0 H_20.

Breathing Resistance

Data analysis indicates subjects wearing the MGMA at the 1 - 1.75" H_20 setting of the A-14 regulator between 1 and 3 ata received ideal percentages of oxygen for use in Air Force hyperbaric therapy. Analysis of the MGMA expired mask cavity carbon dioxide levels does not pose any known physiological threat for hyperbaric use. Subjects stated "when regulator outlet pressure went above 1.75" H_20, it became difficult to exhale". Subject data analysis supports this statement. See figure 12.

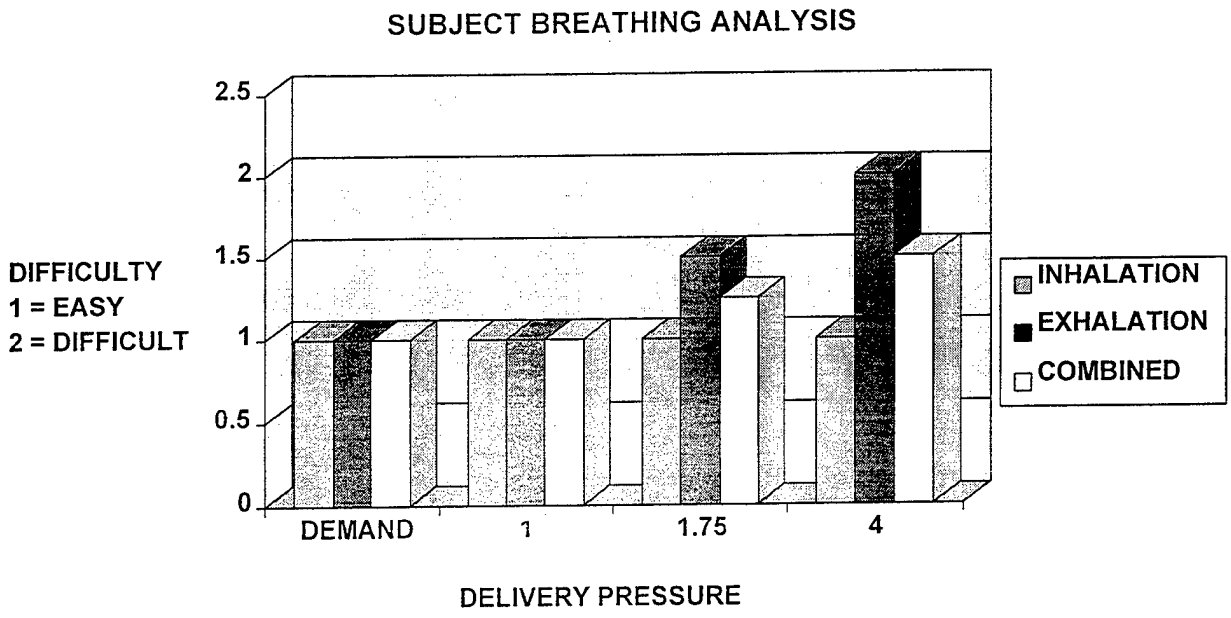

Figure 12

All six subjects noted less breathing resistance during inhalation/exhalation when the regulator delivered 1.75" H_20 or less. Higher then 1.75" H_20 regulator pressure was described as fatiguing.

Comfort & Fit

Subjects wearing the MGMA described the mask as increasing lighter and comfortable to wear in comparison to the current MBU-5/P. The MGMA offered no obstruction to view and is aesthetically appealing. Problems were noted with breathing exhalation and mask leakage as regular pressure increased > 1.75" H_20. Adjustment of the fasteners on the MGMA to the Velcro® on the mesh skullcap was described as awkward and noisy.

CONCLUSION

General guidelines for the use of oxygen breathing devices used by patients and inside observers during hyperbaric treatments are described in an Aviation, Space, and Environmental Medicine article titled "Efficient Oxygen Mask for Patients Undergoing Hyperbaric Oxygen Therapy" by Sheffield, Stork and Morgan: The authors of the article outline the following parameters for the use and approval of these devices:

1. Deliver 100% oxygen under increased ambient pressure.
2. Be capable of a slight positive pressure to compensate for the increased density of respiratory gases at 3 ATA.
3. Allow the use of a nebulizer inline to moisturize the oxygen.
4. Be light enough and comfortable enough to be worn by a sick patient/inside attendant for prolonged periods i.e., 90 min/day, 6 days/week, for as long as 30-45 days.
5. Be capable of exhausting the exhaled gases through oxygen overboard dump system.

Inspiratory and expiratory gas analysis indicate that the MGMA and current A-14 regulator constitute a highly efficient oxygen delivery system for hyperbaric use. MGMA met or exceeded the standards established by Sheffield, Stork and Morgan. Currently, the MGMA is being modified by the Gentex Corporation to evaluate concerns found during and after this study. The mesh skullcap is being modified to reduce noise, the mask hard-shell is being reinforced to prevent cracking and the inhalation/exhalation hoses have been extended in length.

Future development of the oxygen delivery system must consider the evaluation of an oxygen overboard dump system. This study did not evaluate a new overboard dump system, but offered a venturi device shown in figure 5. Currently, the overboard dump system at the Davis Hyperbaric Laboratory facility at Brooks Air Force Base is modified with such a device. Air Force hyperbaric chamber distribution of the MGMA would require modification of the existing overboard dump systems with a device similar to figure 5.

Overall the MGMA is suitable for use in Air Force hyperbaric chambers. At this time, it is recommended that the Air Force evaluate an oxygen overboard dump system with a company such as the Gentex Corporation or Engineering Cybernetics Incorporated.

REFERENCES

1. Air Force Policy Directive 40-4 (Clinical Investigation and Human Use in Medical Research)

2. Air Force Instruction 40-403 (Using Human Subjects in Research, Development, Test, and Evaluation)

3. AFPAM 48 -134, (Hyperbaric Chamber Operations)

4. Division Operating Instruction 41-8 (O_2 Delivery System)

5. Technical Manual 14P3-1-161 (Combined Advanced Technologies Enhanced Design (G) Combat Edge Ensemble Equipment)

6. Technical Manual 15X6-4-2-1 (Oxygen Equipment) 15 October 1994.

7. Paul Sheffield, Roger Stork, Thomas R. Morgan. Efficient O_2 Mask for Patients Undergoing Hyperbaric O_2 Therapy, Aviation, Space, and Environmental Medicine, February 1977

8. National Fire Protection Agency (NFPA) 99. Health Care Facilities Code Chapter 19